IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: WHITE, James M.

SERIAL NO.: 09/596,370 ART UNIT: 1744

FILED: June 19, 2000 EXAMINER: Chorbaji, M. R.

TITLE: BIOLOGICAL FLUID DISPOSAL SYSTEM

REMARKS ON AMENDMENT "B"

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Final Action of May 20, 2004, having a response being due with a one month extension on September 20, 2004 and in conjunction with a Request for Continued Examination, please consider the following remarks in conjunction with the amendments to the above-identified application as follows:

REMARKS

Upon entry of the present amendments, original Claims 1-20 were previously canceled, and Claims 21-35 have been amended. Reconsideration of the rejections, in light of the foregoing amendment and present remarks, is respectfully requested. The present amendments have been entered for the purpose of more clearly distinguishing the present invention from the prior art patents.

In the Final Action of May 20, 2004, it was indicated that Claims 21, 27, 29 and 33 were rejected under 35 U.S.C. §112, first paragraph because these claims fail the written description requirement. The specification fails to reasonably convey that the inventor has possession of the claimed invention at the time of the original filing. Claims 21-25, 29-31 and 33-34 were rejected

under 35 U.S.C. §103(a) as being unpatentable over the Jackson patent in view of the Aubrey patent and further in view of the Kern patent. Claims 26-28, 32 and 35 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Jackson patent in view of the Aubrey patent and further in view of the Kern patent and the Griffiths patent.

In response to the Final Action, Applicant has amended the claims so as to properly distinguish the present invention from the prior art. Claim 21 has been amended to clarify the "valveless" connection between the biological fluid line and the disinfectant line and inter-relationship between the flow of disinfectant and the flow of biological fluid. The valveless connection has been modified to recite "within the housing" in direct response to the Examiner's rejection for failure to comply with the written description requirement. Examiner correctly recognizes that Applicant discloses valves (62 and 54) on the biological fluid line and the disinfectant line. Thus, it is clear that the inventive aspect of the present invention is NOT a completely valveless system, but rather a valveless connection within the housing at the junction of the biological fluid line and the disinfectant line. This structural relationship is important because the present invention allows for easy construction and maintenance, for improved efficiency and for lower costs. The valveless relation at the connection point of the biological fluid line and the disinfectant line is significant because the user is no longer able to adjust flow and control mixture as disclosed in the prior art.

With specific regard to the Examiner's rejection, Applicant has sufficiently described the valveless connection point within the housing of the system. Both Figure 1 and Figure 2, in addition to Page 10 of the specification adequate disclose the valveless junction at the physical connection between the biological fluid line and the disinfectant line. Similar amendments have been made in

Claims 27, 29 and 33 with respect to the clarification of the structure of the "valveless" characteristic of the present invention.

As an overview to the response to the obviousness rejections, independent Claim 21 has been amended to recite that the suction action through the disinfectant line is dependent upon flow of the biological fluid. Claim 24 has been amended to recite the physical connection between the biological fluid line and the disinfectant line in relation to the inlet and water flow line. Claim 25 now includes the proper description of the structural placement of the valve means within the context of the term "valveless" as defined in the base independent Claim 21. Claims 27 and 29 have been similarly amended to properly recite the valveless relation as disclosed in the specification and drawings. Also, Claim 33 has been amended to recite that the flow of biological fluid through the biological fluid line coincides with flow of disinfectant through the disinfectant line. Additionally, Claim 33 now specifies the structural limitation of the valveless relation at the junction between the biological fluid line and the disinfectant line.

Applicant respectfully contends that the features amended into independent Claims 21, 29 and 33 serve to clearly distinguish the present invention from the prior art combination.

It is important to re-assert that the purpose of the present invention is to provide a convenient and easy unit to install in the hospital environment whereby a disinfectant can be mixed with blood prior to passing the biological fluid to the sewer. It was important to provide a self-regulated system with minimal mechanical and electrical devices. The present invention utilizes a unique system of venturi effect, along with orifice relationships, so as to properly mix the components together. This structure is neither shown nor suggested in the prior art patents. The venturi effect has particular

importance with respect to the present invention. As recited on pages 7 and 8 of the original specification:

> The flow of water through the water flow line 14 across the outlet 22 creates a venturi effect so as to create a suction within the pipe 20 for drawing the disinfectant 24 through the disinfectant line 18 and for drawing the biological fluid 26 into and through the biological fluid line 16.

As a result of the structure of the present invention, a static, self-regulated system is created, despite being pumpless and generally valveless. Claim 21 has been amended to reflect this inventive aspect of the present invention. Specifically, the suction through the disinfectant line is dependent upon the flow of biological fluid. As originally disclosed in Figure 1, it is clear that the suction at outlet 22 draws biological fluid through the biological fluid line. As the biological fluid passes over the valveless connection to the disinfectant line, suction draws disinfectant through the disinfectant line. Thus, the invention clearly shows a related venturi effect, wherein the flow of biological fluid across the valveless connection draws the disinfectant through the disinfectant line for mixing. The flow of the disinfectant, as a second fluid, is dependent upon the flow of the biological fluid, as a first fluid. Additionally, as stated in the original specification on page 10, lines 13 - 17.

> An interesting feature of the present invention is that the system is its self-regulation. In any venturi-type system, fluids will flow in the direction of least resistance. When the supply of biological fluid 26 is exhausted from container 50, the inlet 32 will simply suck air therethrough. As a result, no disinfectant 24 will be drawn, at that time, from the container 58. As such, there is no need to monitor the system to shut off the system when the biological fluid supply is exhausted.

The self-regulating characteristic of the present invention is a result of the flow of the biological fluid coinciding with the flow of the disinfectant. The coordinated flow of the two different fluids is significant because the system is pumpless and valveless at the mixing point. Unlike the prior art,

the present invention relies upon this passive-type control to stop the mixture of biological fluid and the disinfectant.

Applicant respectfully contends that the prior art patents do not make this system of the present invention obvious. The present invention is a unique solution of reducing as many internal devices and structures as possible and decreasing the need for monitoring and adjustment, while still maintaining controlled mixture of the two fluids. The present invention greatly reduces mechanical failures and cleaning and maintenance time; however, close attention must be paid to the installation of the system because there are no internal controls to change settings within the housing or at the connection point.

Applicant respectfully contends that the prior art patents, individually or in combination, fail to show the features the present invention as defined herein.

The prior art Jackson patent still teaches an apparatus for the treatment and disposal of infectious waste. The Jackson patent was originally provided by the Applicant as a typical prior art system that is distinguishable from the present invention. The Jackson patent depends upon various pumps and valves within the housing for active control of the mixing and incubation of different liquids and mixtures throughout the system. The Jackson patent provides for heavily controlled and monitored activity, requiring extensive devices and controls.

The prior art Aubrey system is another mixing apparatus employing a variety of pumps and valves, which are required for the specific control and regulation within the housing of the device and at connection points between the liquids to be mixed. Similarly, the Griffiths patent describes a static mixing apparatus 76 for the purpose of mixing the biological fluid with the disinfectant at highly controlled storage points and connection points. A variety of pumps are employed throughout

the system of the Griffiths patent so as to assure the proper delivery and mixture of the components, including valves to change flow directions.

The Kern patent teaches a liquid mixing device for aspirating a mixed cleaning fluid on semiconductors. The Kern patent utilizes a modified venturi effect to control the volume of fluid at the connection point and at the outlet point. This prior art system has multiple parallel injection points relying upon a single venturi effect for regulation. Each of the parallel injection points are independently regulated and controlled, since different chemicals are being injected from each injection point. The amount of monitoring for individual volume and flow rate is high because of the tiny magnitude of fluids to be aspirated.

Relative to the independent claims, as amended herein, Applicant respectfully contends that the combination of the Jackson, Aubrey and Kern patents would not teach the limitations of the amended independent Claim 21. The Aubrey patent does not teach a pumpless and valveless structure within the housing. The Aubrey patent teaches against such a structure because of needed electronic controls regulating fluids (i.e. solenoid valve 64), at different locations within the housing 66. The Kern patent does not teach that the flow of the disinfectant fluid is dependent on the flow of the biological fluid. The concept of venturi and suction by water flow is disclosed; however, the inter-relationship between two fluids with related venturi effects, as now clarified in the amended Claim 21, are not disclosed by the Kern patent. The multiple fluids of the Kern patent are arranged in parallel to allow fine adjustment of individual fluid sources. Furthermore, only one venturi-related effect is taught. As such, all elements of the present invention are not made obvious by the combination of prior art patents.

Relative to Claims 24 and 25, amendments were made to more clearly recite the structure of the connection point of the disinfectant fluid line to the biological fluid line as a pipe. Also, the use

of valve means 62 and 54 were expressly limited to outside the housing and displaced from the connection point of the two fluid lines. These dependent claims are also not made obvious by the combination of the prior art patents. The valve means outside of the housing is taught against in the Aubrey patent, and the connection point of the two fluids is not disclosed by the multiple inlet ports in parallel relation of the Kern patent.

Relative to independent Claims 29 and 33, Applicant respectfully contends that the combination of the Jackson, Aubrey and Kern patents similarly fail to disclose the structure of the present invention as defined by independent Claim 21. Claims 29 and 33 have been amended to clarify the valveless relation at the connection point within the housing, which is not disclosed by the either the Jackson patent or Aubrey patent. Additionally, the coinciding flow of disinfectant and flow of biological fluid flow is not taught by the Kern patent. In fact, the Kern patent teaches against such an arrangement so as to allow the independent adjustment and manipulation of multiple fluids at multiple fluid inlets.

Relative to the remaining obviousness rejections based upon the combination of the Jackson patent, Aubrey patent, Kern patent and the Griffiths patent, Applicant respectfully contends that Claims 26-28, 32 and 35 are not made obvious by this combination. The first Jackson, Aubrey and Kern combination does not disclose the elements nor even suggest the elements of the base independent claims, such that the addition of the Griffiths patent provides no further argument for making these dependent Claims 26-28, 32 and 35 obvious.

With general regard to the obviousness rejections, Applicant respectfully contends that it is clear that only components of random prior art systems are joined together for the purposes of "making obvious" the teachings of claims. There would be no natural reason for combining the biological fluid disposal of the Jackson patent with the X-ray chemicals of the Aubrey patent and the

semi-conductor chip aspirator of the Kern patent. Fundamentally, it is very difficult to see how the unrelated fields of art can be combined, in any way. The amounts, toxicity, volatility, function, and application of mixed fluids encounter widely different obstacles and considerations. These combinations are from entirely different fields of art, each of which is very unrelated from the field of biological fluid disposal. Applicant respectfully notes that combining four disparate prior art patents in different fields actually tends to support a finding a nonobviousness.

Based upon the foregoing analysis, Applicant contends that independent Claims 21, 29 and 33 are now in proper condition for allowance. Additionally, those claims which are dependent upon these independent claims should also be in condition for allowance. Reconsideration of the rejections and allowance of the claims at an early date is earnestly solicited. Since no new claims have been added above those originally paid for, no additional fee is required.

Respectfully submitted,

9.17.04
Date

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